

### REMARKS

This paper is a Response to the Office Action mailed December 3, 2008. Claims 1 to 11 are pending. Claims 6 and 9 are under consideration. New claims 12 to 15, which depend from either of claims 6 or 9 have been added. Accordingly, upon entry of this paper, claims 6, 9 and 12 to 15 are under consideration.

#### Regarding the Amendments

The amendments to the claims are supported throughout the specification. In particular, the amendment to recite the specifically identified sequences is supported, for example, by originally filed claims 6 and 9; at page 23, lines 6-11; and at page 24, lines 16-19. The amendment to recite "90% or more identity" is supported, for example, at page 27, lines 23-32. The amendment to recite that "the combination has a nitrile hydratase activity" is supported, for example, at page 17, lines 17-20; and page 18, line 23, to page 19, line 12. Thus, as the claim amendments are supported by the specification, no new matter has been added and entry thereof is respectfully requested.

#### Regarding the New Claims

New claims 12 to 15 are supported throughout the specification. In particular, claim 12 is supported, for example, at page 32, lines 1-26. Claims 13 to 15 are supported, for example, by originally filed claims 6 and 9; at page 23, lines 6-11; at page 24, lines 16-19; and at page 27, lines 23-32. Thus, as claims 12 to 15 are supported by the specification, no new matter has been added and entry thereof is respectfully requested.

#### I. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

The rejection of claims 6 and 9 under 35 U.S.C. §112, first paragraph, as allegedly lacking an adequate written description and enablement is respectfully traversed. The grounds for rejection are set forth in the Office Action, pages 3-6.

Claims 6 and 9 as originally filed are adequately described. Nevertheless, solely in order to further prosecution of the application and without acquiescing to the propriety of the rejection, the claims have been amended as set forth above. The rejection will therefore be addressed with respect to the amended and new claims 12 to 15.

A proper analysis for written description under 35 U.S.C. §112, first paragraph is whether one skilled in the art can reasonably conclude that the inventor had possession of the

claimed invention. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); see, also, *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985). To satisfy the written description requirement, “Applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art.” *In re Angstadt*, 537 F.2d 498, 502-503 (CCPA 1976), *Utter v. Hiraga*, 845 F.2d 993, 998-99 (Fed. Cir. 1988). Thus, a description of every nitrile hydratase  $\alpha$  or  $\beta$  subunit sequence having 90% or more identity to the recited sequences is not required. Furthermore, the Federal Circuit held “that (1) examples are not necessary to support adequacy of a written description (2) the written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and (3) there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.” *Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006). Thus, in view of the standard set by the court, a genus can be adequately described under 35 U.S.C. §112, first paragraph without specific examples, an actual reduction to practice, or a known structure of any nitrile hydratase  $\alpha$  subunit or  $\beta$  subunit variant of the recited sequences.

Here, the claims specify both structure and function, and in view of the guidance in the specification, which discloses numerous sequences of nitrile hydratase  $\alpha$  subunits and  $\beta$  subunits, the 90% or more identity to the referenced nitrile hydratase  $\alpha$  and  $\beta$  subunits required of the claims, and the knowledge in the art regarding conserved sequence motifs of nitrile hydratase  $\alpha$  subunits and  $\beta$  subunits, the skilled artisan would be apprised of an adequate number of nitrile hydratase  $\alpha$  subunits and  $\beta$  subunits within the genus of claims 6, 9 and 12 to 15.

The specification teaches 5 nitrile hydratase  $\alpha$  subunits and 2 nitrile hydratase  $\beta$  subunits. Each of these sequences have 90% or more identity to at least one of the recited sequences. In view of the foregoing, one skilled in the art would know several nitrile hydratase  $\alpha$  and  $\beta$  subunit amino acid sequences having the specified 90% or more identity.

In addition to the numerous nitrile hydratase  $\alpha$  and  $\beta$  subunit amino acid sequences disclosed in the specification having 90% or more identity, knowledge of nitrile hydratase  $\alpha$  and  $\beta$  subunit structure and function is known to one of skill in the art. For example, nitrile hydratase  $\alpha$  subunits are characterized by a conserved motif, namely CXXCSC. This motif, which is present in all nitrile hydratase  $\alpha$  subunits, coordinates a cobalt ion for catalytic

activity. Consequently, one of skill in the art would know that nitrile hydratase  $\alpha$  subunit variants having 90% or more identity would have the sequence CXXCSC.

Nitrile hydratase  $\beta$  subunits are also characterized by a conserved motif, namely D-X-[G/A]-G at the N-terminus. A version of this conserved sequence motif, namely D-[M/L/I]-G-G is in all nitrile hydratase  $\beta$  subunits disclosed in the application. Consequently, one of skill in the art would know that nitrile hydratase  $\beta$  subunit variants having 90% or more identity would have the conserved sequence motif, D-[M/L/I]-G-G.

Thus, in view of the guidance of the specification of various nitrile hydratase  $\alpha$  and  $\beta$  subunit sequences, and the high degree of sequence identity to particular nitrile hydratase  $\alpha$  and  $\beta$  subunit sequences, when combined with the knowledge in the art concerning nitrile hydratase  $\alpha$  and  $\beta$  subunit structure and function at the time of the invention, the skilled artisan would know other nitrile hydratase  $\alpha$  and  $\beta$  subunit sequences with 90% or more identity to the recited sequences that would retain at least partial nitrile hydratase activity. Consequently, the skilled artisan would be apprised of a number of nitrile hydratase  $\alpha$  and  $\beta$  subunits within the scope of the claims.

In sum, the written description requirement under 35 U.S.C. § 112, first paragraph may be satisfied without actually producing variant nitrile hydratase  $\alpha$  and  $\beta$  subunit sequences. Here, in view of the fact that the specification discloses numerous nitrile hydratase  $\alpha$  and  $\beta$  subunit sequences having the required 90% or more identity to the referenced nitrile hydratase  $\alpha$  and  $\beta$  subunits, that the claimed sequences must have 90% or more identity to the recited sequences, and the knowledge in the art regarding conserved sequence motifs of nitrile hydratase  $\alpha$  subunits and  $\beta$  subunits, the skilled artisan would be apprised of an adequate number of nitrile hydratase  $\alpha$  subunits and  $\beta$  subunits within the claimed genus. Consequently, the skilled artisan would be apprised of a representative number of nitrile hydratase  $\alpha$  and  $\beta$  subunit sequences within the claims. As such, an adequate written description of is provided, and Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph as allegedly lacking an adequate written description be withdrawn.

II. REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

The rejection of claims 6 and 9 under 35 U.S.C. §112, second paragraph, as allegedly indefinite is respectfully traversed. The grounds for rejection are set forth in the Office Action, pages 6-7.

Claims 6 and 9 as originally filed are clear and definite under 35 U.S.C. §112, second paragraph. Nevertheless, solely in order to further prosecution of the application and without acquiescing to the propriety of the rejection, the claims have been amended as set forth above. The rejection will therefore be addressed with respect to the amended claims.

Claims 6 and 9, as amended, recite particular sequence identifiers for nitrile hydratase  $\alpha$  and  $\beta$  subunit sequences. Amended claims 6 and 9 also no longer recite “with such known protein sequences.” Thus, in view of the amendments the grounds for rejection are moot and Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph be withdrawn.

III. REJECTION UNDER 35 U.S.C. §102

The rejection of claims 6 and 9 under 35 U.S.C. §102(b) as allegedly anticipated by Falon *et al.* (WO 97/12964) is respectfully traversed. Allegedly, Falon *et al.* describe each and every element claimed, as set forth on page 7 of the Office Action.

Claims 6 and 9 as originally filed are neither taught nor suggested by Falon *et al.* Nevertheless, solely in order to further prosecution of the application and without acquiescing to the propriety of the rejection, the claims have been amended as set forth above. The rejection will therefore be addressed with respect to the amended and new claims 12 to 15.

Falon *et al.* fail to teach or suggest each and every element of claims 6, 9 and 12 to 15. In particular, none of the recited sequences nor any protein sequences with 90% or more identity to any of the recited sequences are taught or suggested by Falon *et al.* Consequently, as Falon *et al.* fail to teach or suggest claims 6, 9 and 12 to 15, the rejection under 35 U.S.C. §102(b) is improper and must be withdrawn.

IV. DOUBLE PATENTING

Claims 6 and 9 stand rejected due to obviousness-type double patenting over claim 1 of US Patent No. 7,288,402. Claims 6 and 9 stand provisionally rejected due to obviousness-

type double patenting over claims 1, 2, 9 and 15 of co-pending US application no. 12/296,057.

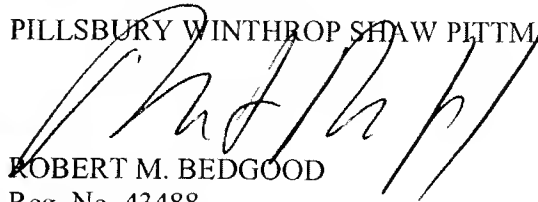
Applicants respectfully request that the Examiner hold the rejection in abeyance until allowable subject matter is indicated. After allowable subject matter has been indicated Applicants will address the rejections.

In summary, for the reasons set forth herein, Applicants maintain that the claims clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 509-4065. Please charge any fees associated with the submission of this paper to Deposit Account Number 033975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

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**CERTIFICATION UNDER 37 C.F.R. §§ 1.8 and/or 1.10\***

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